REMARKS

Reconsideration and allowance of the application is respectfully requested. Claims 1, 3, 4, 6-9, 11, 12 and 14-16 were in the application, claim 15 has been amended.

The examiner rejected claim 15 as having insufficient antecedent basis. Claim 15 has been amended to depend from claim 4, rendering this rejection moot.

Claims 1, 3, 5, 6-9, 11, 12, 14 and 16 were rejected under 35 U.S.C. §102(e) as being anticipated by Sandstrom, U.S. Patent No. 6,613,015.

The Sandstrom patent was filed on October 4, 2001. The present application has a filing date of February 4, 2002, and enclosed herewith is a Declaration under 37 CFR.1.131 by the inventor, Thomas Frederick Enns, with supporting documentation establishing a conception and reduction to practice of the invention prior to October 4, 2001. Consequently, the Sandstrom patent is not prior art and this rejection is moot.

Claims 1, 3, 4, 6-9, 11, 12, and 14-16 were rejected under 35 U.S.C. §102(e) as being anticipated by Barrus et al, WO02/45574. The effective filing date of Barrus et al is December, 2001, and the above-referenced Declaration establishes a conception and reduction to practice of the invention, prior to December, 2001. Consequently, the Barrus et al application is not prior art and this rejection is moot.

Claims 1, 3, 4, 6, 11, 12 and 14-16 were rejected under U.S.C. §102(b) as being anticipated by Lusson, DE4426784. For the examiner's convenience, a translation of the German patent is enclosed herewith.

Under U.S.C. §102, anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. W.L. Gore & Assocs., Inc. v. Garlock, Inc., 220 USPQ 303 (Fed.Cir. 1983). All the limitations in the claims must be found in the reference, since the claims measure the invention. In re Lange, 209 USPQ 288, 293 (CCPA 1981). Further, the reference must

describe the applicant's claimed invention sufficiently to have placed a person of ordinary skill in the art in possession of the invention. In re Spada, 15 USPQ 2d 1655 (Fed. Cir. 1990).

Lusson does not anticipate the applicant's invention. In particular, claim 1 requires "a rigid spine located above the spacer and the handles, the rigid spine including a first portion of the L-shaped needle therein." Claim1 also requires the handles to have "distal ends movable into contact with each other... the handles engaging the spine when the distal ends are in contact."

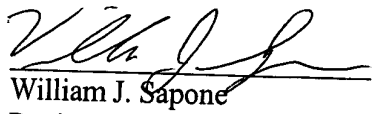
There is nothing in Lusson that shows a "rigid spine" located above the spacer that includes the L-shaped needle therein, nor can the wings 44 of Lusson move into contact with each other and a rigid spine.

The wings 44 of the Lusson flex downwardly to protect the needle to prevent inadvertent contact, the device having curved portions 40 and 42 to inhibit the wings 44 and 46 from "taking a horizontal position", as stated at Page 6, Lines 7-12. Thus, these handles are not grasped during insertion, and cannot be moved into contact, as they engage the needle, not a spine of the device.

As each and every element is not present, claims 1, 3, 4, 6, 11, 12, 14-16 are not anticipated by by Lusson.

Based on the above amendments and remarks, reconsideration and allowance of the application is respectfully requested. However should the examiner believe that direct contact with the applicant's attorney would advance the prosecution of the application, the examiner is invited to telephone the undersigned at the number given below.

Respectfully submitted,



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Perfusion apparatus with protective wings

There is described a perfusion apparatus with a needle (38) which can be inserted through a septum of an access location implanted in a patient, in order to be able to inject, into a catheter, a medication originating in a perfusion line, wherein the apparatus has two wings (44, 46) positioned on either side of the needle (38) and able to be folded together around the needle when the needle is withdrawn from its location of use, such as to avoid sticking the person withdrawing the needle (38) from the said location. The withdrawal of the needle from its location of use requires simple pressure with the fingers against the wings (44, 46), the ends of which rest against the skin of the patient.

Description

The invention relates to a perfusion device incorporating a needle which can be inserted into the septum of an access location, the septum being implanted in or on a patient, in order to be able to inject a medication into a catheter, the medication being derived from a perfusion line.

For a considerable time, catheters have been known which can be implanted under the skin of a patient, access thereto being provided by a delivery apparatus. When perfusion of the patient is to be carried out, for example a periodical chemical therapeutic treatment, the doctor or medical assistant determines by feel where the septum is located, and then inserts the perfusion needle through the skin of the patient into the septum.

When the doctor withdraws the perfusion needle out of the septum, there is always the risk that he will stick himself with the needle, even when he takes steps to avoid it. This is a major risk, if the patient is suffering from an illness which is transmitted through the blood. Examples of such illnesses are: AIDS, viral hepatitis and other viral illness.

In view of the above, it is an object of the present invention to provide a perfusion apparatus which avoids any risk of being stuck by the perfusion needle when the latter is withdrawn from the location of use.

In accordance with the invention, this object is attained by way of a perfusion apparatus having a needle which can be inserted into a septum of an access location or an access device that is implanted on or in a patient, in order to inject, into a catheter, a medication that is derived from a perfusion line. Two wings are provided on opposite sides of the needle, and these are folded on either side of the needle when the latter is

to be withdrawn from its perfusion position. By this means, any risk that the caregiver will be stuck by the needle is avoided.

The invention is described in greater detail below, where further important characteristics are described. The illustrations show:

In Figure 1 a perspective view of a first example embodiment of an apparatus in accordance with the invention, wherein the wings are illustrated in the stretched-out condition, in which they are not folded about the needle;

In Figure 2 a schematic side view of the apparatus of Figure 1, wherein the wings are folded about the needle;

In Figure 3 a perspective view of a second example embodiment of the apparatus in accordance with the invention, wherein the wings are likewise not folded about the needle;

In Figure 4 a bottom plan view of the apparatus according to Figure 3;

In Figure 5 a plan view of the underside of a wing, in accordance with the example embodiment of Figures 3 and 4.

Figure 1 shows a first example embodiment of a perfusion apparatus in accordance with the invention. This includes a needle 10 which can be inserted into an access location or an access device which is implanted under the skin of a patient. The lumen of the perfusion needle is in communication with a tube 12 at right angles, the tube 12 ending in an end piece 14. The end piece can be constructed as a Luer-locking device, which is in communication with the perfusion line through which the medication in question can be distributed. Though not shown in the drawings, there is provided a bacteriological filter ahead of the end piece 14 of the perfusion line, and/or after the end piece of the conduit 12, the filter having the effect of restraining bacteria and air

bubbles. The filter can be given an enhanced effect by providing another filter intended to remove the very fine particles.

The perfusion device has a grip which can be grasped with the thumb and forefinger, in order to insert the needle into the access device, and also to withdraw the needle therefrom. The withdrawal can however be differently designed, specifically on the basis of the present invention, as is more specifically described below.

The grip 16 is elongated at both ends by a support 18 which likewise may be made of plastic, such that the grip and the supports can be molded integrally, and indeed can be made integral with the entire perfusion apparatus. On each support 18 there is provided a cushion 20, for example made of polyurethane foam. The supports 18 with their grips 20 lie against the skin of the patient, if the needle is correctly inserted into the access apparatus. These portions have the task of stabilizing the perfusion apparatus, and of preventing the needle from being bent or displaced sidewardly, thereby avoiding any risk of error.

The perfusion apparatus illustrated in Figure 1 has two wings 22, 24, which are oppositely aligned when the needle is inserted into the septum. When the care-giver (doctor or nurse) carrying out the perfusion pulls the needle out after the end of the perfusion, it is sufficient to exert pressure on the wings with the fingers, thus pressing the wings down against the skin of the patient to either side of the access device. The needle is then simply pulled out. At the end of the withdrawal of the needle, the two wings end up in a downwardly folded-together position, and indeed due to their connection with the perfusion apparatus, throughout the essentially complete withdrawal of the needle, whereby the wings are connected through hinges to the body of the apparatus. Thus the needle, in this position, is protected on both sides by the wings.

In contrast to the state of the art, wherein the needle is first withdrawn with the help of the grip, and then the two wings are folded together to protect the needle, the withdrawal in accordance with a device according to the invention takes place as a single step. This is made possible by the wings, and it turns out that during the withdrawal of the needle from the position of use, the caregiver undergoes no risk of being stuck unwillingly by the needle, because the fingers, including the thumb are protected constantly by the wings.

Figure 2 shows the Figure 1 apparatus in the condition in which both wings 22, 24 are partially folded together. Figure 2 shows that each wing can have lines of weakness, the figure showing only a single line of weakness 26. The line of weakness divides the wing into two or more flaps, which function to facilitate the folding together of the wing(s) around the needle 10.

Figure 2 shows that the wings can be locked together, specifically with the help of a clip having a male portion 28 on the inside of one wing, and a female portion 30 on the inside of the other part (an error in the original German: the author clearly meant to use the word "wing"), in alignment with the male part. Consequently, the needle, which is in any event shorter than the wings, is protected between the two wings, and there is thus no danger of being stuck by the needle, which as described above would entail tangible risks, all arising during those manipulations which are consequent upon the actual perfusion with the help of the apparatus.

The perfusion apparatus with the needle protected by the wings, can then been thrown away or pasteurised prior to being re-used.

A second embodiment of the apparatus in accordance with the invention is illustrated in Figures 3, 4 and 5. Figure 3 shows the apparatus in a perspective view,

from which it is evident that a base 32 of the apparatus supports a cushion 33 made of foamed polyurethane. A feed conduit 34 is connected to a catheter, and a grip 36 is provided, along with a needle 38. The apparatus has, in its upper portion, two elements 40, 42 which are preferably circularly curved. Two wings 44, 46 are provided which, just as in the first embodiment, have lines of weakness 48. The wings are connected to the base at lines of weakness 50, which thus function as hinges.

Figure 4 shows a plan view of the apparatus according to Figure 3, seen from below, in which the wings 44, 46 each have two parts 52, each of which overlaps the edge of the corresponding circularly curved elements 40, 42. When the wings are in the position shown in Figure 3 and 4, they are maintained in this position. Thereby they define a specific angle (for example about 35°) with the horizontal, due to the fact that the circularly curved elements prevent the wings from taking a horizontal position.

If the apparatus is delivered with the wings in a horizontal position, i.e., each wing being in alignment with the other wing, it suffices to exert a small pressure on the wing in order to cause the part 42 of the wing, reacting into the applied force, to slip under the circularly curved portions 40, 42 of the base. This takes place before the apparatus is installed for perfusion.

Figure 5 shows the inner surface of the wing of the second embodiment in accordance with Figure 3. The wing has a cylindrical recess 54 in which the needle 38 is lodged when the two wings are folded together. The recess terminates in an elliptical part 56, which receives the point of the needle 38. At the end of the wing is provided a clip, for example in the form of a curvilinear clip 58 adjacent to the elliptical part 56 of the recess. One of the wings, for example, the wing 44, has a male part of the clip in the shape of a projection, preferably of circular shape, whereas the other wing 46 has

the female part of the clip, specifically in a correspondingly formed recess, likewise of circular configuration, so that the male part can be pressed into the female part.

In the second embodiment, the sloping position of the wings makes it possible to apply a lesser grip on the apparatus with the thumb and forefinger, or with fingers, in order to withdraw the needle after perfusion is completed, followed by the protective inward folding-together of the wings, without risking a wound from the needle.

The apparatus in accordance with the invention can be manufactured simply and at low cost, because all of its elements can be made from plastic by casting, for example from polyurethane, and preferably in a single working step. However, the apparatus can also be made to consist of several parts, whereby the wings can be attached to the actual apparatus with the help of hinges. It will be evident that the apparatus in accordance with the invention can be modified in many ways.